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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|------------------------------------------------------------------------------|-------------|----------------------|----------------------|------------------|
| 10/783,723 | 02/20/2004 | Reynaldo A. Osorio | 1759.17207-FOR DIV 2 | 6618 |
| 26308 | 7590 | 12/26/2006 | EXAMINER | |
| RYAN KROMHOLZ & MANION, S.C. POST OFFICE BOX 26618 MILWAUKEE, WI 53226 | | | CUMBERLEDGE, JERRY L | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3733 | |
| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE | | |
| 3 MONTHS | 12/26/2006 | PAPER | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

| Office Action Summary | Application No. | Applicant(s) |
|------------------------------|------------------------|---------------------|
| | 10/783,723 | OSORIO ET AL. |
| Examiner | Art Unit | |
| Jerry Cumberledge | 3733 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

WARNING: NO FEE IS DUE IF THIS COMMUNICATION IS NOT RECEIVED BY THE FILING DATE OF THE PATENT.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on ____.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 6-20 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 6-20 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on 20 February 2004 is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 29/06/2005 11/04/2004

4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ .

5) Notice of Informal Patent Application

6) Other: ____ .

DETAILED ACTION

Priority

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows: The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosures of the prior-filed applications, Application No. 60/194,685 and Application No. 09/134,323, fail to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. The stated applications fail to provide support for claim 14, which includes a stent. Adequate support for a stent is found in Application No. 09/827,260, of which the current application is a divisional application. As such, the Effective Filing Date of claim 14 is the filing date of Application No. 09/827,260, or 04/05/2001.

Specification

Applicant is reminded of the proper content of an abstract of the disclosure.

A patent abstract is a concise statement of the technical disclosure of the patent and should include that which is new in the art to which the invention pertains. If the

patent is of a basic nature, the entire technical disclosure may be new in the art, and the abstract should be directed to the entire disclosure. If the patent is in the nature of an improvement in an old apparatus, process, product, or composition, the abstract should include the technical disclosure of the improvement. In certain patents, particularly those for compounds and compositions, wherein the process for making and/or the use thereof are not obvious, the abstract should set forth a process for making and/or use thereof. If the new technical disclosure involves modifications or alternatives, the abstract should mention by way of example the preferred modification or alternative.

The abstract should not refer to purported merits or speculative applications of the invention and should not compare the invention with the prior art.

Where applicable, the abstract should include the following:

- (1) if a machine or apparatus, its organization and operation;
- (2) if an article, its method of making;
- (3) if a chemical compound, its identity and use;
- (4) if a mixture, its ingredients;
- (5) if a process, the steps.

Extensive mechanical and design details of apparatus should not be given.

Specifically, the Applicant is requested to include more details regarding the presently claimed invention (e.g. more information regarding the void creating device and the claimed method) in the abstract.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 6-8 and 15-20 are rejected under 35 U.S.C. 101 because they are drawn to non-statutory subject matter. In claim 6, lines 1-4, applicant positively recites part of a human, i.e. "A vertebral body including a native cancellous bone volume that has been altered to comprise a layer of cancellous bone that has been compressed to form a compressed bone region that peripherally defines a cavity and another region of substantially uncompressed cancellous bone occupying at least a portion of the

remaining native cancellous bone volume." Thus claims 6-8 and 15-20 include a human within their scope and are non-statutory.

A claim directed to or including within its scope a human is not considered to be patentable subject matter under 35 U.S.C. 101. The grant of a limited, but exclusive property right in a human being is prohibited by the Constitution. *In re Wakefield*, 422 F.2d 897, 164 USPQ 636 (CCPA 1970).

Claims 9-14 are rejected under 35 U.S.C. 101 because they are drawn to non-statutory subject matter. In claim 9, lines 1-5, applicant positively recites part of a human, i.e. "A vertebral body including a native cancellous bone volume that has been altered to comprise a layer of cancellous bone that has been compressed to form a compressed bone region that peripherally defines a cavity...and another region of substantially uncompressed cancellous bone occupying at least a portion of the remaining native cancellous bone volume." Thus claims 9-14 include a human within their scope and are non-statutory.

A claim directed to or including within its scope a human is not considered to be patentable subject matter under 35 U.S.C. 101. The grant of a limited, but exclusive property right in a human being is prohibited by the Constitution. *In re Wakefield*, 422 F.2d 897, 164 USPQ 636 (CCPA 1970).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 6-12 and 15-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Scholten et al. (US Pat. 4,969,888).

Scholten et al. disclose a vertebral body including a native cancellous bone volume that has been altered to comprise a layer of cancellous bone that has been compressed to form a compressed bone region that peripherally defines a cavity and another region of substantially uncompressed cancellous bone occupying at least a portion of the remaining native cancellous bone volume (column 6, lines 47-62). Column 6, lines 47-62 describe the process of inserting an initial balloon that expands, which is used to center a second balloon. As the initial balloon expands, it will compress cancellous bone, but not all of the cancellous bone, leaving a layer of cancellous bone that has been compressed to form a compressed bone region that peripherally defines a cavity and another region of substantially uncompressed cancellous bone occupying at least a portion of the remaining native cancellous bone volume. One can see that the initial balloon cannot have compressed all of the cancellous bone, since the cancellous bone is further compressed by the second balloon (column 7 lines 17-21). The

compressed bone region comprises a barrier (column 7, lines 21-25). The compressed bone region comprises a shell (column 7, lines 21-25).

Scholten et al. disclose a vertebral body including a native cancellous bone volume that has been altered to comprise a layer of cancellous bone that has been compressed to form a compressed bone region that peripherally defines a cavity, a bone filling material in the cavity (column 7, lines 32-35), and another region of substantially uncompressed cancellous bone occupying at least a portion of the remaining native cancellous bone volume (column 6, lines 47-62). The compressed bone region comprises a barrier substantially inhibiting extravazation of a bone filling material from the cavity (column 7, lines 21-25). The compressed bone region comprises a shell substantially inhibiting extravazation of a bone filling material from the cavity (column 7, lines 21-25). The bone filling material comprises bone cement (column 7, lines 32-35).

Scholten et al. disclose a method for treating a native vertebral body to create a vertebral body as defined in claim 6 (column 6, lines 47-62). The method further comprises placing a bone filling material into the cavity (column 7, lines 32-35). The method comprises inserting a void creating device (Fig. 20, ref. 65) into the native cancellous bone volume and manipulating the void creating device to compress the first layer of cancellous bone and form the cavity (column 6, lines 47-62). The method further comprises placing a bone filling material into the cavity (column 7, lines 32-35). The method comprises inserting an expandable void creating device (Fig. 20, ref. 65) into the native cancellous bone volume and expanding the void creating device to

compress the first layer of cancellous bone and form the cavity (column 6, lines 47-62). The method further comprises placing a bone filling material into the cavity (column 7, lines 32-35).

With regards to statements of intended use and other functional statements (e.g. "...a barrier substantially inhibiting extravasation of a bone filling material from the cavity..."), they do not impose any structural limitations on the claims distinguishable over the device of Scholten et al., which is capable of being used as claimed if one so desires to do so. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Furthermore, the law of anticipation does not require that the reference "teach" what the subject patent teaches, but rather it is only necessary that the claims under attack "read on" something in the reference. *Kalman v. Kimberly Clark Corp.*, 218 USPQ 781 (CCPA 1983). Furthermore, the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 6-13 and 15-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Scholten et al. (US Pat. 4,969,888) in view of Kuslich (US Pat. 5,571,189).

Scholten et al. disclose the claimed invention except for the bone filling material comprising bone graft material.

Kuslich discloses using a graft material as a bone filling material (column 9, lines 53-55), in order to promote bone fusion across a gap (column 9, lines 53-55).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have used the bone graft material of Kuslich as the bone filling material of Scholten et al., in order to promote fusion across a gap (column 9, lines 53-55).

Claims 6-12 and 14-20 rejected under 35 U.S.C. 103(a) as being unpatentable over Scholten et al. (US Pat. 4,969,888) in view of Felt et al. (US Pat. 6,306,177).

Scholten et al. disclose the claimed invention except for the bone filling material comprising a stent.

Felt et al. disclose the bone filling material comprising a stent (column 20, lines 64-67 and column 21, lines 1-3), which is used to form an implant in situ (column 21, lines 1-3).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have used the bone filling material comprising a stent of Felt

et al. with the device of Scholten et al., in order to form an implant in situ (column 21, lines 1-3).

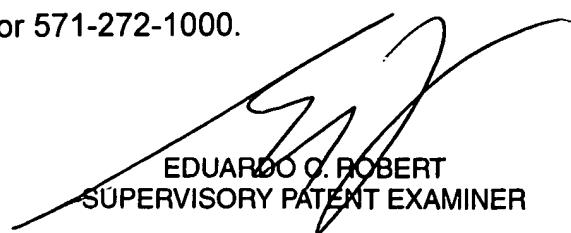
Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Please see attached PTO-892.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jerry Cumberledge whose telephone number is (571) 272-2289. The examiner can normally be reached on Monday - Friday, 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



EDUARDO O. ROBERT
SUPERVISORY PATENT EXAMINER

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